

Listing of Claims

Claims 1-90 canceled.

91. (previously presented) A method for reducing the level of active biological contaminants or pathogens in a serum, plasma or protein sample, said method comprising:

(i) adding to said serum, plasma or protein sample at least one stabilizer wherein said at least one stabilizer is selected from the group consisting of dimethylsulfoxide (DMSO), trehalose, and mannitol; wherein the stabilizer is not an extraneous protein or a type II quencher, and wherein the sample does not contain a sensitizer; and

(ii) irradiating said serum, plasma or protein sample with a dose of gamma radiation effective to reduce the level of active biological contaminants or pathogens in said serum, plasma or protein sample.

92. (previously presented) The method of claim 91 wherein said serum, plasma or protein sample is at a temperature below ambient temperature during irradiation.

93. (previously presented) The method of claim 92 wherein said temperature is below -20°C during irradiation.

94. (previously presented) The method of claim 92 wherein said temperature is below -40°C during irradiation.

95. (previously presented) The method of claim 92 wherein said temperature is below -60°C during irradiation.

96. (previously presented) The method of claim 92 wherein said temperature is below -78°C during irradiation.

97. (previously presented) The method of claim 92 wherein said temperature is below -196°C during irradiation.

98. (previously presented) The method of claim 91 wherein said serum, plasma or protein sample is maintained in an inert atmosphere during irradiation.

99. (previously presented) The method of claim 91 wherein said serum, plasma or protein sample is maintained under vacuum during irradiation.

100. (previously presented) The method of claim 91 wherein the protein sample comprises an antibody, immunoglobulin, hormone, growth factor, anticoagulant, clotting factor, complement protein, or lipo-protein.

101. (previously presented) The method of claim 100 wherein the clotting factor is selected from the group consisting of Factor I (fibrinogen), Factor II (prothrombin), Factor III (tissue factor), Factor V (proaccelerin), Factor VI (accelerin), Factor VII (proconvertin, serum prothrombin conversion), Factor VIII (antihemophilic factor A), Factor IX (antihemophilic factor B), Factor X (Stuart-Prower factor), Factor XI (plasma thromboplastin antecedent), Factor XII (Hageman factor), Factor XIII (protransglutaminase), von Willebrands factor (vWF), Factor Ia, Factor IIa, Factor IIIa, Factor Va, Factor VIa, Factor VIIa, Factor VIIIa, Factor IXa, Factor Xa, Factor XIa, Factor XIIa and Factor XIIIa.

102. (previously presented) The method of claim 100 wherein the immunoglobulin is a polyclonal or monoclonal immunoglobulins or mixtures thereof.

103. (previously presented) The method of claim 102 wherein the immunoglobulin is immunoglobulin G, immunoglobulin M, immunoglobulin A, immunoglobulin E or mixtures thereof.

104. (previously presented) The method of claim 91 wherein the protein sample contains one or more proteins selected from the group consisting of protein C, protein S, alpha-1 anti-trypsin (alpha-1 protease inhibitor), heparin, insulin, butyl-cholinesterase, warfarin, streptokinase, tissue plasminogen activator (TPA), erythropoietin (EPO), urokinase, neupogen, antithrombin-3, alpha-glucosidase, hemoglobin and albumin.

105. (previously presented) The method of claim 91 wherein the protein sample contains one or more proteins produced by recombinant methods.

106. (previously presented) The method of claim 91 wherein the protein sample contains a plasma protein fraction.

107. (previously presented) The method of claim 106 wherein the plasma protein fraction is selected from the group consisting of Plasma-Plex®, Protenate®, Plasmanate® and Plasmatein®.

108. (previously presented) The method of claim 91 wherein the serum sample contains fetal bovine serum.

109. (previously presented) The method according to claim 91 wherein said irradiation is applied at a rate of at least about 3 kGy/hour to at least about 45 kGy/hour.

110. (previously presented) The method of claim 91 wherein the at least one stabilizer is propylene glycol.

111. (previously presented) The method of claim 110 wherein the concentration of propylene glycol is about 1.0 to about 2.2 M.

112. (previously presented) The method of claim 91 wherein a combination of two or more stabilizers is added to said plasma, serum or protein sample.

113. (canceled)

114. (previously presented) The method of claim 91 wherein the concentration of DMSO is about 1.0 to about 3.1 M.

115. (previously presented) The method of claim 91 wherein the concentration of mannitol is about 135 to about 150 mM.

116. (previously presented) The method of claim 91 wherein the concentration of trehalose is about 1 to about 100 mM.

117. (canceled)

118. (previously presented) The method of claim 91 wherein the sample contains one or more residual solvents.

119. (previously presented) The method of claim 118 wherein the residual solvent is water.

120. (previously presented) The method of claim 118 wherein the residual solvent is a non-aqueous solvent.

121. (previously presented) The method of claim 118 wherein the residual solvent content is reduced prior to irradiation.

122. (previously presented) The method of claim 121 wherein the residual solvent content is reduced to about six to about eight percent.

123. (previously presented) The method of claim 121 wherein the residual solvent content is reduced by a process selected from the group consisting of lyophilization, drying, concentration, evaporation, chemical extraction, spray drying and vitrification.

124. (previously presented) The method of claim 91 wherein the total dose of gamma irradiation is at least about 25 kGy.

125. (previously presented) The method of claim 91 wherein the total dose of gamma irradiation is at least about 45 kGy.

126. (previously presented) The method of claim 91 wherein the total dose of gamma

irradiation is at least about 75 kGy.

127. (previously presented) A composition produced by the method of claim [[1]] 91.

128. (previously presented) A composition produced by the method of claim 110.

129. (previously presented) A composition produced by the method of claim 111.

130. (previously presented) A composition produced by the method of claim 112.

131. (canceled)

132. (previously presented) A composition produced by the method of claim 114.

133. (previously presented) A composition produced by the method of claim 115.

134. (previously presented) A composition produced by the method of claim 116.